

U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE		DATE: 4 May 2006 (04.05.2006)
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		10/578260 U.S. PAT. NO. If known Not Yet Assigned
INTERNATIONAL APPLICATION NO.: PCT/JP2003/014243	INTERNATIONAL FILING DATE: 10 November 2003 (10.11.2003)	PRIORITY DATE CLAIMED: none
TITLE OF INVENTION: INSULIN EXPRESSING HUMAN PANCREATIC ISLET CELL LINE CAPABLE OF REVERSIBLY PROLIFERATING AND USE THEREOF		
APPLICANT(S) FOR DO/EO/US: TANAKA, Noriaki; KOBAYASHI, Naoya; NARUSHIMA, Michiki; TANAKA, Yoshihito		
Applicant hereby submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <u>X</u> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <u> </u> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <u>X</u> This is an express request to begin national examination procedures (35 USC 371(f)). The submission must include items(5), (6), (9) and (21) indicated below.</p> <p>4. <u>X</u> The US has been elected (Article 31).</p> <p>5. <u>X</u> A copy of the International Application as filed (35 U.S.C. 371(c)(2)):</p> <p>a. <u>X</u> is transmitted herewith (required only if not transmitted by the International Bureau).</p> <p>b. <u> </u> has been communicated by the International Bureau.</p> <p>c. <u> </u> is not required, as the application was filed in the United States Receiving Office (RO/US)</p> <p>6. <u>X</u> A English translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p>7. <u>X</u> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <u> </u> are attached hereto (required only if not transmitted by the International Bureau).</p> <p>b. <u> </u> have been communicated by the International Bureau.</p> <p>c. <u> </u> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <u>X</u> have not been made and will not be made.</p> <p>8. <u> </u> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <u>X</u> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <u> </u> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>		
ITEMS 11 to 20 BELOW CONCERN OTHER DOCUMENT(S) OR INFORMATION INCLUDED:		
<p>11. <u>X</u> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <u>X</u> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <u>X</u> A FIRST preliminary amendment.</p> <p>14. <u> </u> A SECOND or SUBSEQUENT preliminary amendment</p> <p>15. <u> </u> A substitute specification.</p> <p>16. <u> </u> A change of power of attorney and/or address letter.</p> <p>17. <u> </u> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter2 and 35 USC 1821 - 1825</p> <p>18. <u> </u> A second copy of the published international application under 35 USC 154(d)(4)</p> <p>19. <u> </u> A second copy of the English language translation of the international application under 35 USC 154(d)(4)</p> <p>20. <u>X</u> Other items or information:</p> <p>TRANSMITTAL LETTER WITH FEE CALCULATION; ENGLISH TRANSLATION OF APPLICATION WHICH CONSISTS OF 32 PAGES INCLUDING: 2 COVER SHEETS OF THE PUBLICATION, 21 PAGES TEXTUAL SPECIFICATION, 2 PAGES OF 5 CLAIMS, 1 PAGE OF THE ABSTRACT; 6 SHEETS DRAWINGS WITH FIGS. 3 & 5 AS COLOR PHOTOGRAPHS; PRELIMINARY AMENDMENT WITH ATTACHMENT A AND B TO BE EXAMINED; PETITION FOR COLOR PHOTOGRAPHS UNDER 37 CFR § 1.84(b) WITH 2 SETS OF COLOR PHOTOGRAPHS (TO MAKE 3 SETS) AND 1 SET OF BLACK & WHITE FOR FIGS 3 & 5; EXECUTED INVENTOR'S DECLARATION; EXECUTED ASSIGNMENT AND RECORDATION COVER SHEET TO NORIAKI TANAKA, OF OKAYAMA, JAPAN; NAOYA KOBAYASHI OF OKAYAMA, JAPAN AND KURARAY MEDICAL INC. OF OKAYAMA, JAPAN; PCT/ISA/210 INTERNATIONAL SEARCH REPORT; INFORMATION DISCLOSURE STATEMENT; PTO FORM 1449 CITING 8 REFERENCES WITH 8 REFERENCES ATTACHED; PCT/IPEA/409 INTERNATIONAL PRELIMINARY EXAMINATION REPORT (IN JAPANESE, ENGLISH TRANSLATION NOT YET AVAILABLE); PCT/IB/308 NOTICE OF COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES; PCT/IB/332 INFORMATION CONCERNING OFFICES NOTIFIED OF THEIR ELECTION; RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT (FERM BP-08R61) AND ENGLISH TRANSLATION IN PART; VIABILITY STATEMENT WITH ENGLISH TRANSLATION IN PART.</p>		

1AP20R334P37/PTO 04 MAY 2006

U.S. APPLICATION NO.
(if known) Not Yet Assigned
10/578260

INTERNATIONAL APPLICATION NO.
PCT/JP2003/014243

DATE: 4 May 2006 (04.05.2006)

21. Basic national fee \$ 300

22. Examination fee

If the written opinion prepared by the ISA/US or the international preliminary examination report prepared by IPEA/US and all claims satisfy Provisions of PCT Article 33(1)-(4) \$ 0

All other situations..... \$200

23. Search fee (37 CFR 1.492(b))

If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$ 0

Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100

International Search Report prepared and provided to the Office..... \$400

All other situations..... \$500

___ Additional fee for specification and drawings filed in paper over 100 sheets (excluding Sequence listing or computer program listing filed in an electronic medium).
The fee is \$250 for each additional 50 sheets of paper or fraction thereof.

TOTAL OF 21, 22 & 23 =

CALCULATIONS

PTO USE ONLY

\$ 300

\$ 200

\$ 400

\$

\$ 900

Surcharge of \$130.00 for furnishing the oath or declaration later than ___ 20
___ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).

\$

CLAIMS	NO. FILED	NO. EXTRA	RATE		
TOTAL	6 - 20 =	0	X \$ 50.00	\$	0.00
INDEPENDENT	1 - 3 =	0	X \$ 200.00	\$	0.00
Multiple dependent claims(s) (if applicable)			+ \$360.00	\$	0.00
TOTAL OF ABOVE CALCULATIONS =				\$	900.00
Reduction by 2 for asserting small entity, if applicable. (Note 37 CFR 1.9, 1.27, 1.28).				\$	0.00
SUBTOTAL =				\$	900.00
Processing fee of \$130.00 for furnishing the English translation later than ___ 20 ___ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	0.00
TOTAL NATIONAL FEE =				\$	900.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	40.00
Petition Fee set forth Under 37 CFR 1.17(i) for Submission of Color Photographs Under 37 CFR § 1.84(a) and 1.84(b).				\$	130.00
TOTAL FEES ENCLOSED =				\$	1,070.00
Amount to be:					
refunded				\$	
charged				\$	

05/15/2006 GFREY1 00000060 10578260

05 FC:146 130.00 OP

ATTORNEY'S DOCKET NO: 27385U

U.S. APPLICATION NO.

(if known, not yet assigned)

INTERNATIONAL APPLICATION NO.

PCT/ JP2003/014243

DATE: 4 May 2006 (04.05.2006)

10/578260

- a. ☒ Two checks in the aggregate amount of \$ 1,070.00 to cover the above fees are enclosed.
- b. ☐ Please charge my Deposit Account No. 14-0112 in the amount of \$ _____ to cover the above fees. (A duplicate copy of this sheet is enclosed.)
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0112.
- d. Fees are to be charged to a credit card ☐ WARNING: Information on this form may become public ☐ Credit Card Information should not be included on this form. ☐ Provide credit card information and authorization on PTO-2038

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed to request that the application be restored to pending status.

Send All Correspondence To:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

TANAKA et al.

International Application No. PCT/JP2003/04203

Serial No. NOT YET ASSIGNED

International Filing Date: 10 November 2003 (10.11.2003)

Filed: May 4, 2006For: **INSULIN EXPRESSING HUMAN PANCREATIC ISLET CELL LINE CAPABLE
OF REVERSIBLY PROLIFERATING AND USE THEREOF****10/578260****AP20 Rec'd FCT/PTO 04 MAY 2006**TRANSMITTAL LETTER

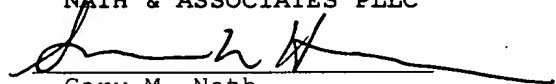
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

**Submitted herewith for filing in the U.S. Patent and Trademark
Office is the following:**

- (1) Transmittal Letter
- (2) Transmittal Letter To U.S. Designated/Elected Office (DO/EO/US)
Concerning Filing under 35 U.S.C. 371
- (3) International Publication No: WO 2005/045026 A1
International Publication Date: 19 May 2005 (19.05.2005)
With English translation which consists of 32 pages including:
 - 2 Cover Pages of the Publication,
 - 21 pages Textual Specification,
 - 2 pages of 5 Claims,
 - 1 page of the Abstract,
 - 6 sheets of Drawings with figs. 3 & 5 as color photographs;
- (4) Preliminary Amendment with Attachment A & B to be examined;
- (5) Petition for Color Photographs Under 37 CFR § 1.84(b) with 2
additional sets of color photographs for figs. 3 & 5 (to make 3
sets) and 1 set of back & white for figs. 3 & 5;
- (6) Executed Inventor's Declaration;
- (7) Executed Assignment and Recordation Cover Sheet to Noriaki
**TANAKA, of Okayama, JAPAN; Naoya KOBAYASHI of Okayama, JAPAN and
KURARAY MEDICAL INC. of Okayama, JAPAN;**
- (8) PCT/ISA/210 International Search Report;
- (9) Information Disclosure Statement;
- (10) PTO Form 1449 citing 8 references with 8 references attached;
- (11) PCT/IPEA/409 International Preliminary Examination Report (in
Japanese, English translation not yet available)
- (12) PCT/IB/308 Notice of Communication of the International
Application to the Designated Offices;
- (13) PCT/IB/332 Information Concerning Offices Notified of their
Election;
- (14) Receipt in the Case of an Original Deposit (FERM BP-08461) and
English translation in part;
- (15) Viability Statement with English translation in part;
- (16) Check No. 2074 \$940.00 for Government Filing Fee(\$300),
Search Fee(\$400) and Examination Fee(\$200), and Recordation
Fee(\$40);
- (17) Check No. 2015 \$ 130.00 Petition Fee set forth under 1.17(i);
- (18) Postcard for early notification of serial number.

Respectfully submitted,
NATH & ASSOCIATES PLLC

By:



Gary M. Nath
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Date: May 4, 2006
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